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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,427	11/26/2003	Jim Mottola	37621/279.1	1046
69821 7590 01/12/2009 MERIT MEDICAL SYSTEMS, INC. C/O STOEL RIVES, LLP ONE UTAH CENTER 201 SOUTH MAIN STREET -- SUITE 1100 SALT LAKE CITY, UT 84111			EXAMINER STIGELL, THEODORE J	
			ART UNIT 3763	PAPER NUMBER
			MAIL DATE 01/12/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/724,427

**Applicant(s)**

MOTTOLA ET AL.

**Examiner**

THEODORE J. STIGELL

**Art Unit**

3763

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 and 13-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 13-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S5108)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

**DETAILED ACTION**

***Response to Amendment***

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/3/2008 has been entered.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Howell (3,949,745). Howell discloses a delivery system that could be used to intravenously deliver contrast media comprising a media reservoir (10), a spike (14a) for accessing contrast media in the reservoir the spike having an inner lumen, a drainage bore (18) positioned on a distal end of the inner lumen, a venting lumen (14), a venting bore positioned on a distal end of the venting lumen, wherein the drainage bore is positioned at a lower elevation than the venting bore when the spike is positioned in the contrast media reservoir (see Figure 1), a length of tubing (16, 24, 26) linked to the spike, a

primer bulb (38) connected in-line with the length of tubing, wherein the primer bulb is compressible to transmit air from a position downstream from the spike, through the spike and into the contrast media source and thereby create a head of pressure above the contrast media in the contrast media reservoir to facilitate the flow of contrast media into the length of tubing, a valve mechanism (42, 44) providing a fluid tight seal to isolate the reservoir, length of tubing, and primer bulb from the inflow of air from the external environment.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2, 4-18, and 26-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howell (3,949,745) in view of Daoud (5,423,346). Howell discloses most of the limitations recited in the claims listed above (see previous rejection), but fails to explicitly teach including a venting door at the end of the venting lumen in order

to selectively equalize the media reservoir. Daoud discloses a similar assembly in which the vented spike (32) includes a venting door (not numbered). One of ordinary skill in the art would recognize that the venting door would allow for selective equalization. Therefore, it would have been obvious at the time of the invention to modify the device of Howell with the venting door of Daoud in order to provide an assembly that allowed for selective equalization and thus ensured proper delivery of the media.

Claims 1-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manzie (5,505,707) in view of Daoud (5,423,346). Manzie discloses most of the limitations recited in the claims listed above (see previous rejection), but fails to explicitly teach a vented spike with a venting door at the end of a venting lumen. Daoud discloses a similar assembly in which the spike assembly is a vented spike (32) with a venting door (not numbered). One of ordinary skill in the art would recognize that the vented spike assembly would allow for selective equalization. Therefore, it would have been obvious at the time of the invention to modify the device of Manzie with the vented spike assembly of Daoud in order to provide an assembly that allowed for selective equalization and thus ensured proper delivery of the media.

### ***Response to Arguments***

Applicant's arguments filed 12/3/2008 have been fully considered but they are not persuasive. In response to the applicant's argument that Howell does not disclose the limitations recited in claim 22, the examiner respectfully disagrees. Howell appears to show that the venting bore is located higher than the drainage bore. See Figure 1.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to THEODORE J. STIGELL whose telephone number is (571)272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Theodore J Stigell/  
Examiner, Art Unit 3763

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763

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